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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,137	04/21/2004	Philip C. Gevas	ACG2BUSA	6164

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EXAMINER	
BORIN, MICHAEL L	
ART UNIT	**PAPER NUMBER**
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,137	GEVAS ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,18-24,26-32 and 57-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,18-24,27-32 and 57-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/25/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Amendment filed 10/25/2006 is acknowledged. Claims 16,17,25, 33-56 are canceled. Claims 57-59 are added. Claims 15, 18-24, 26-32, 57-59 are pending.

Claim 30 remains withdrawn from consideration as being directed to non-elected species (proton pump inhibitors were elected as species of an agent).

2. Applicant's arguments have been fully considered and they are deemed to be persuasive-in-part. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102 and 103.

3. Claims 15,21-24,27-29,57 are rejected under 35 U.S.C. 102(b) as anticipated by Watson et al (Cancer Research, 1996).

Claim 15 is amended to remove the limitation of administering agent (such as proton pump inhibitor). The instant claims are directed to method for treating hypergastrinemia by administering an immunogenic composition comprised of a G17 fragment SEQ ID No. 1 (which is nine N-terminal residues of gastrin) .

Watson et al teach immunogen, Gastrimmune, which is composed of nine N-terminal residues of gastrin (G17) linked to immunogenic carrier, such as diphtheria toxoid. Administration of Gastrimmune to mice with gastric cancer caused generation of anti-G17 antibodies which in turn triggered about 40% reduction in gastrin level (p. 883, right column). Two trophic forms of gastrin, G17 and glycine-extended G17 are being neutralized (p. 884, left column, bottom). Thus, the reference teaches that administration of Gastrimmune resulted in reduction of gastrin level, i.e., the effect as instantly claimed. As for the term, "hypergastrinemia", both the reference and the Background section of the instant application teach that level of gastrin are elevated in patients with gastric cancer; thus it is assumed that the mice treated in the reference had gastrin level elevated compared to normal individuals.

4. Claims 18-20 are rejected under 35 U.S.C.103(a) as obvious over by Watson et al (Cancer Research, 1996).

In regard to dependent claims 18-20, if there are any differences between Applicant's claimed methods and that of the prior art, the differences would be appear minor in nature. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable conditions for treatment of patient having hypergastrinemia such as target levels of gastrin, order of administration, etc., which are art recognized result-effective variables which would have been routinely determined in the art.

5. Claims 57,58,59,26,31,32 are rejected under 35 U.S.C.103(a) as unpatentable over admitted prior art (Background section) in view of Watson et al (Cancer Research, 1996, or Int. J. Cancer, 1995) or Gevas et al (US Patent 5,607,676).

New claim 58, and claims now dependent thereupon, address method of treatment hypergastrinemia wherein another agent, such as a proton pump inhibitor, is also being administered.

It is well known that administering proton pump inhibitors to subjects having excess gastric acid results in hypergastrinemia, i.e., elevated level of gastrin peptides (such as G17 peptide), and that, in turn, hypergastrinemia leads to such complications as increased production of gastric acid, and gastric tumors. See Background Section, p. 1-2, or see Gevas et al, col. 1-2. Therefore, it is obvious that such side effects of proton pump blockers are undesirable and need to be treated or prevented.

Watson et al. reference is applied as discussed above. The reference teaches reduction in gastrin levels in mice suffering from stomach cancer (and having elevated level of gastrin peptides) caused by administration of Gastrimmune, which is immunogenic composition comprising G17 peptide, reduces gastrin level *in vivo.*

Gevas et al (US Patent 5,607,676[1]) teaches teach composed of G17 fragments, such as nine N-terminal residues of gastrin (e.g., col. 5, line 50), linked to immunogenic carrier, such as diphtheria toxoid. Said immunogen generates anti-gastrin antibodies

[1]as well as other US patents of these applicants (Gevas et al. are the inventors of the instant invention as well) listed in Information Disclosure Statement filed 03/20/2001.

which reduce level of gastrin and inhibit hypergastrinemia related disorders. Gevas teaches importance of neutralizing gastrin levels (col. 2-3).

It would be *prima facie* obvious to one of ordinary skills in the art at the time the invention was made to be motivated to use the anti-gastrin immunogen of Watson et al or Gevas et al to reduce level of gastrin and thus to inhibit hypergastrinemia related disorders, because it would limit the side effects caused by administration of proton pump blockers.

Response to arguments

Applicant argues that Background Section does not provide any teaching or admission that hypergastrinemia is a condition for treatment. Examiner respectfully disagrees. The Background section teaches that patients with pernicious anemia (PA) are hypergastrinemic (about 40-times elevated total gastrin level; p. 1, lines 11,12), that the degree has significant positive correlation with the fundic enterochromaffin-like cells (p. 2, lines 9-11, 25-28) , and hypergastrinemia may be responsible for development of gastric cancer in PA patients (p. 3,top). Thus, specification clearly suggests that hypergastrinemia is undesirable event leading to development of disorders. In addition, the Background section teaches that hypergastrinemia is a side effect of administration of proton pump inhibitors (p. 3, bottom).

Conclusion.

6. No claims are allowed

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb